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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
WESTERN DIVISION

JERRY BODIE, Plaintiff, v. PURDUE PHARMA COMPANY; PURDUE PHARMA L.P.; PURDUE PHARMA INC.; PURDUE FREDERICK COMPANY; P.F. LABORATORIES, INC.; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC., Defendant.	)	Case No.: CV-02-2838-VEH

MEMORANDUM OPINION REGARDING MOTION FOR SUMMARY JUDGMENT

I. JURISDICTION AND VENUE

This is a diversity action, 28 U.S.C. §1332. Plaintiff is a citizen of Alabama, all Defendants are business entities organized and having their principal place of business in states other than Alabama. The amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00) exclusive of interests and costs. The acts complained of are alleged to have taken place in the Northern District of Alabama.

Bodie's Complaint alleges five (5) different theories of recovery, one per count:

- product liability;

- breach of implied warranty of merchantability;

- negligence;

- malicious conduct; and

- fraud, misrepresentation and suppression.

Before the court is all Defendants' (collectively "Purdue") Motion for Summary Judgment (doc. 82) on all counts of Plaintiff Jerry Bodie's ("Bodie") claims. Bodie's claims against Purdue are failure to warn and fraud. Purdue's primary defense is the "learned intermediary" doctrine. The parties have filed briefs and voluminous exhibits. After a hearing, the court having considered the evidentiary submissions, the briefs and arguments of counsel, the court concludes that:

1. Purdue has adduced sufficient evidence in support of its Motion to shift the burden to Bodie to come forward with evidence showing material facts in dispute that must be resolved by the trier of fact.

2. Bodie has not come forward with sufficient evidence to overcome Purdue's motion on the warning claims.

3. Bodie has not come forward with sufficient evidence to overcome Purdue's motion on the fraud claims.

Therefore, Purdue's Motion for Summary Judgment is due to be granted as to

all counts of the Complaint.

II. UNDISPUTED FACTS

This product liability case involves the prescription medication OxyContin® Tablets ("OxyContin"). OxyContin is an opioid analgesic pain medication manufactured and marketed by Purdue. It is a Schedule II controlled substance.

On November 25, 1998, Bodie was prescribed OxyContin by physicians treating him for neck and back pain. Bodie's treating physicians (for pain) were Dr. Eugene Mangieri and Dr. Gabriel Fernandez. Both doctors specialize in the treatment of chronic pain.

During Bodie's first visit, November 25, 1998, Dr. Mangieri prescribed 30 mg/day of OxyContin. Bodie has testified that Dr. Mangieri told him that OxyContin was a "new drug" and "he called it a miracle drug, that it was not addictive, had very few side effects, constipation being probably the primary thing and that could be managed by medication or whatever". Bodie also testified that he expressly asked Dr. Mangieri whether OxyContin was addictive. Bodie further testified that he recalls reading a "pamphlet" and information on a "website", which he cannot recall precisely, but which he believes contained information similar to the statements he remembers being made by Dr. Mangieri. Bodie did not retain the pamphlet. No pre-1999 Purdue documentation regarding OxyContin has been offered as evidence.

Bodie testified that he was concerned about becoming addicted. He says he expressly asked Dr. Mangieri about the addictiveness of OxyContin, that he read the Purdue pamphlet and website, and that he would not have taken OxyContin if he had known it was addictive.

Bodie continued taking OxyContin until March, 2002. His initial dosage of 30 mg/day was incrementally increased, during the first year that he took OxyContin, up to 400 mg/day. For the majority of the remaining years he took OxyContin, his daily dose remained between 320 and 400 mg/day.

Dr. Mangieri initially directed Bodie to take OxyContin every eight (8) hours. However, as a result of statements made by a Purdue sales representative to Dr. Mangieri, Dr. Mangieri changed Bodie's prescription to every twelve (12) hours. When the dosage frequency was changed to every twelve (12) hours, the dosage amount was also increased.

Bodie took the medication exactly as prescribed; there is no evidence that he ever abused the medication. Bodie's pain was dramatically reduced initially. However, at some point in late 2001, or early 2002, Bodie's pain began increasing again. He became very sedentary and was "zombie like." No one wanted anything to do with him except his dog. He decided to stop taking OxyContin.

To avoid withdrawal symptoms, Dr. Fernandez began gradually reducing

Bodie's dosage. Bodie's medical records indicate that, as of February 13, 2002, this process was going well and Bodie was experiencing no side effects.

In early March, 2002, Bodie was suffering from anxiety[1] and told Dr. Patrick Bruce Atkins that he wanted to be admitted to the hospital to be taken off OxyContin rapidly. Dr. Atkins admitted Bodie to the hospital and detoxified him of OxyContin over a nine (9) day period. During his inpatient treatment, Bodie was described as "a model patient" who "did remarkably well." Three (3) days after his discharge, Bodie was readmitted to the hospital for further treatment; he stayed an additional three (3) days. Since his second discharge, Bodie has not taken OxyContin.

During his detoxification, Bodie suffered withdrawal pain. After his second discharge from the hospital, Bodie has managed his neck and back pain by taking non-narcotic pain medications.

Dr. Mangieri testified he received and read the OxyContin package insert warnings (and all periodic letters indicating changes to the warnings). There is no evidence that Purdue told Dr. Mangieri or Dr. Fernandez that OxyContin was "virtually non-addictive," or less addictive than other opioids. Dr. Mangieri testified he knew that OxyContin is a Schedule II drug and he knew Schedule II drugs have

[1]Bodie experienced anxiety before he began taking OxyContin and continued to do so after he stopped taking OxyContin.

"the potential to cause addiction in certain patients." Throughout the time that Dr. Mangieri has been prescribing Schedule II drugs, including OxyContin, Dr. Mangieri has known that "additional" restrictions are imposed by the federal government on Schedule II drugs, as opposed to the lower scheduled drugs, because of the greater potential for abuse and addiction regarding Schedule II drugs.

Although no pre-2000 package insert has been introduced into evidence in this case, the 2000 package insert states, in part:

> **DRUG ABUSE AND DEPENDENCE (Addictions)**
>
> OxyContin® is a mu-agonist opioid with an abuse liability similar to morphine and is a Schedule **II** controlled substance. Oxycodone products are common targets for both drug abusers and drug addicts. Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug.
>
> Drug addiction (drug dependence, physiological dependence) is characterized by a preoccupation with the procurement, hoarding, and abuse of drugs for non-medicinal purposes. Drug dependence is treatable, utilizing a multi-disciplinary approach, but relapse is common. Iatrogenic "addiction" to opioids legitimately used in the management of pain is very rare. "Drug seeking" behavior is very common in addicts. Tolerance and physical dependence in pain patients are *not* signs of psychological dependence. Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control. Most chronic pain patients limit their intake of opioids to achieve a balance between the benefits of the drug and dose-limiting side effects.
>
> Physicians should be aware that psychological dependence may not be accompanied by concurrent tolerance and symptoms of physical

> dependence in all addicts. In addition, abuse of opioids can occur in the absence of true psychological dependence and is characterized by misuse for non-medical purposes, often in combination with other psychoactive substances.
>
> OxyContin consists of a duel-polymer matrix, intended for oral use only. Parenteral venous injection of the tablet constituents, especially talc, can be expected to result in local tissue necrosis and pulmonary granulomas.

Again, no pre-2000 "pamphlet" has been produced in evidence but a 2000 pamphlet, which Bodie has testified is "similar" to the pamphlet he read in 1998, before taking OxyContin, says, in part[2]:

> [Question]
> Aren't opioid pain medications like OxyContin® Tablets "addicting?" Even my family is concerned about this.
>
> [Answer]
> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful. If you or your family have concerns about addiction, please talk to your doctor or another member of your healthcare team. This fear should not stand in the way of relief from your pain.

Bodie has failed to present any evidence that any different package insert warnings about addiction dosing frequency, or medication "respites," would have made a difference in Dr. Mangieri's decision to prescribe OxyContin every 12 hours continuously (without respites). Bodie did not ask Dr. Mangieri if his medication

[2]The quoted language is the same in Bodie's (undated) Exhibit 21 and in Purdue's (dated) Exhibit A.

decisions would have been different had he seen or been told about the earlier information Bodie claims to have read. Bodie's expert, Dr. Uhe, testified that "[t]he information about the primary physicians, the marketing motivations,[3] and so on is not sufficiently revealed in the records that I've looked at in detail to really know."

Bodie has failed to present any evidence that Bodie is or ever was addicted to OxyContin. His retained psychiatric expert, Dr. William Jacobs, testified that Bodie was not and is not addicted to OxyContin. The evidence is undisputed, however, that Bodie was diagnosed, during inpatient de-tox, with iatrogenic narcotics dependence, that OxyContin is an iatrogenic narcotic, that OxyContin was the only narcotic prescribed to Bodie after 1998, and there is no evidence to suggest that he took any other narcotic.

III. SUMMARY JUDGMENT STANDARD

Under Fed. R. Civ. P. 56(c), summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Chapman v. AI Transport, 229 F.3d 1012, 1023 (11th Cir. 2000). The party asking for summary judgment always bears the initial

[3]As to dosage frequency - every 12 hours versus every 8 hours.

responsibility of informing the court of the basis for its motion, and identifying those portions of the pleadings or filings which it believes demonstrate the absence of a genuine issue of material fact. Celotex, 477 U.S. at 323. Once the moving party has met its burden, Rule 56(e) requires the non-moving party to go beyond the pleadings and, by its own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial. Celotex, 477 U.S. at 324.

The substantive law will identify which facts are material and which are irrelevant. Chapman, 229 F.3d at 1023; Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). All reasonable doubts about the facts and all justifiable inferences are resolved in favor of the non-movant. Chapman, 229 F.3d at 1023; Fitzpatrick v. City of Atlanta, 2 F.3d 1112, 1115 (11th Cir. 1993). A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." Anderson, 477 U.S. at 248; Chapman, 229 F.3d at 1023. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted. Anderson, 477 U.S. at 249.

The method used by the party moving for summary judgment to discharge its initial burden depends on whether that party bears the burden of proof on the issue at trial. See Fitzpatrick, 2 F.3d at 1115-17 (citing U.S. v. Four Parcels of Real

Property, 941 F.2d 1428 (11th Cir. 1991)(*en banc*)). If the moving party bears the burden of proof at trial, then it can only meet its initial burden on summary judgment by coming forward with positive evidence demonstrating the absence of a genuine issue of material fact; i.e. facts that would entitle it to a directed verdict if not controverted at trial. Fitzpatrick, 2 F.3d at 1115. Once the moving party makes such a showing, the burden shifts to the non-moving party to produce significant, probative evidence demonstrating a genuine issue for trial.

If the moving party does not bear the burden of proof at trial, it can satisfy its initial burden on summary judgment in either of two ways. First, the moving party may produce affirmative evidence negating a material fact, thus demonstrating that the non-moving party will be unable to prove its case at trial. Once the moving party satisfies its burden using this method, the non-moving party must respond with positive evidence sufficient to resist a motion for directed verdict at trial.

The second method by which the moving party who does not bear the burden of proof at trial can satisfy its initial burden on summary judgment is to affirmatively show the absence of any evidence in the record in support of a judgment for the non-moving party on the issue in question. This method requires more than a simple statement that the non-moving party cannot meet its burden at trial but does not require evidence negating the non-movant's claim; it simply requires the movant to

point out to the court that there is an absence of evidence to support the non-moving party's case. Fitzpatrick, 2 F.3d at 1115-16. If the movant meets its initial burden by using this second method, the non-moving party may either point to evidence in the court record, overlooked or ignored by the movant, sufficient to withstand a directed verdict, or the non-moving party may come forward with additional evidence sufficient to withstand a directed verdict motion at trial based on the alleged evidentiary deficiency. However, when responding, the non-movant can no longer rest on mere allegations, but must set forth evidence of specific facts. Lewis v. Casey, 518 U.S. 343 (1996) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992)).

IV. ANALYSIS

As noted, Count One of the Complaint is for strict product liability. Count Two is for breach of implied warranty of merchantability. Count Three is for negligence. Count Four is for malicious conduct. Count Five is for fraud, misrepresentation and suppression.

A. Warning claims

As stated in Bodie's brief, "[t]he gravamen of Plaintiff's Complaint is that Purdue failed to warn Mr. Bodie's doctor of OxyContin's defects." (Opposition brief at 12.)

1. Count One - Strict Product Liability

In Count One, Bodie asserts his failure to warn claim as a strict liability claim. "Such a claim is not viable under Alabama law[4], where the Alabama Supreme Court has specifically retained concepts of negligence in products liability cases and has rejected notions of any no-fault liability. (Citations omitted.)" Brasher v. Sandoz Phar. Corp., 2001 LEXIS 18364, [*43] (N.D. Ala. Sept. 21, 2001).[5]

2. Count Two - Breach of Implied Warranty of Merchantability

As stated previously, Bodie has stated that the "gravamen" of all his claims are Purdue's failure to (adequately) warn his physician. Thus, Count Two will be analyzed under the learned intermediary doctrine.

> It is well settled in Alabama that, in cases involving pharmaceutical companies selling prescription drugs, the learned intermediary doctrine applies. See, e.g., Stone v. Smith, Kline & French Last., 731 F.2d 1575, 1579-80 (11th Cir. 1984).

Brasher, supra, at [*45] .

> Under Alabama law, to prevail in a warnings claim, the plaintiffs also must demonstrate a causal link between the allegedly inadequate warning and the injury. . . . [T]his means that the plaintiffs must demonstrate that, had the defendant given an adequate warning, it would have been read and heeded by the prescribing physicians. See, e.g.,

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[4] This action is a diversity of citizenship action, and the substantive rule of decision is supplied by Alabama law. Erie RR v. Tompkins, 58 S.Ct. 817 (1938).

[5] Not to be confused with the same case found at 160F.Supp.2d 1291 (N.D. Ala. 1291), which discusses medical causation and Daubert issues.

Gurley v. American Honda Mtr. Co., 505 So.2d 358, 361 (Ala. 1987). Brasher, supra, 2001 LEXIS 18364, at [*48].

In this case, there is simply no evidence offered by Bodie that, had Purdue given a more adequate warning, Dr. Mangieri would have altered the product or dosage he prescribed to Bodie. Bodie complains of three areas of inadequate warnings: (1) addictiveness; (2) dosage frequency; and (3) the need for "breaks" in treatment (the respite issue).

As to addictiveness, Bodie argues that his testimony that Dr. Mangieri told Bodie that OxyContin was safe and virtually non-addictive, together with promotional materials given to sales representatives and sales methods employed by those representatives, is sufficient evidence to present to a jury Bodie's theory that Purdue "must have" understated to Dr. Mangieri OxyContin's addictiveness.

Bodie, as "the nonmovant[,] need not be given the benefit of every inference but only of every reasonable inference." Frontier Ins. Co. v. International, Inc., 124 F.Supp.2d 1211, 1213 (N.D. Ala. 2000). Mere speculation is not reasonable. Bodie never asked Dr. Mangieri if he would have prescribed differently for Bodie if he (Dr. Mangieri) had known what Bodie alleges are the true statistics about OxyContin's addictiveness. Further, Dr. Mangieri testified that he knew OxyContin was a Schedule II drug and that Schedule II drugs are addictive. Where it is shown that a

physician was aware of the possible risks involved in the use of a particular drug, yet chose to use it regardless of the adequacy of the warning, then, as a matter of law, the adequacy of the warning was not a proximate cause of the injury. See, Stewart v. Janssen Pharmaceutica, Inc., 780 S.W.2d 910 (Tex. App. El Paso 1989), writ denied (Feb. 21, 1990). (Where a doctor testified that he was familiar with the drug Sufenta and had previously used it, stated that he was clearly aware that respiratory depression occurs with any anesthetic, both in the operating room and thereafter, and acknowledged that anyone receiving an anesthetic should be closely observed for respiratory depression, the court found that even if there was a deficiency in the warning as to the dangers of the drug, it was not a proximate cause of the injury.)

As to dosage frequency, there is no evidence that, had Bodie been dosed at a different frequency than every 12 hours, he would not have become "dependent" on OxyContin.[6] "Under Alabama law, to prevail in a warning claim, the plaintiffs also must demonstrate a causal link between the allegedly inadequate warning and the injury." Brasher, supra, at [*48].

There is a similar total lack of evidence of proximate causation between the failure to warn that respite breaks were necessary and Bodie's injury. That is, there is no evidence that respite breaks would have prevented Bodie's dependence on

[6]As stated previously, there is no evidence that Bodie was or is "addicted" to OxyContin.

OxyContin.

3. Count Three - Negligence

For the reasons stated under section 2., *supra*, Bodie's claim for negligence fails for lack of any evidence that the allegedly inadequate warning proximately caused Bodie's injury.

4. Count Four - Malicious Conduct

For the reasons stated under section 2., supra, Bodie's claim for malicious conduct fails for lack of any evidence that the allegedly inadequate warning proximately caused Bodie's injury.

5. Count Five - Fraud, Misrepresentation and Suppression

Bodie does not argue that Purdue's failure to warn Bodie creates liability on Purdue's part. Rather, Bodie argues that: (1) Purdue made false representations to Bodie that OxyContin was "safe' and "non-addictive;" (2) that Purdue knew those representations were false when they were made; (3) that Bodie would not have taken OxyContin but for Purdue's representations; and (4) that Bodie was harmed thereby.

To allow a patient to assert such a claim against a pharmaceutical manufacturer would undermine the whole purpose of the learned intermediary doctrine: the manufacturer's obligation is to adequately warn the doctor; the doctor uses his medical judgment to decide whether the risks of a particular medication outweigh the

benefits for a particular patient. See, Toole v. Baxter Healthcare Corp., 235 F.3d 1307 (11th Cir. 2000). (Under Alabama law, a manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product.) See also, Brasher, supra , 2001 LEXIS 18364, at [*45] (The learned intermediary doctrines "provides a limited exception to the general rule that the manufacturer must warn the 'foreseeable user,' . . . of the hazards posed by its product.")

Specifically, "the court rel[ies] on the expertise of the physician intermediary to bridge the gap in . . . [prescription drug] cases where the product and related warning are sufficiently complex so as not to be fully appreciated by the consumer"; "'[u]nder the 'learned intermediary' doctrine, the adequacy of . . . [the pharmaceutical manufacturer's] warning is measured by its effect on the physician, . . . to whom it owed a duty to warn, and not by its effect on . . . [the patient]." Toole v. Baxter Healthcare Corp., 235 F.3d 1307, 1314.

When it adopted the 'learned intermediary' doctrine, the Alabama Supreme Court did so with these words:

> Plaintiffs-appellants misconceive the physician's role in prescribing ethical drugs, and the significance of a drug manufacturer's warnings in undertaking that responsibility. A proper understanding of that role has been articulated by the United States Court of Appeals for the Fifth Circuit as follows:

> We cannot quarrel with the general proposition that where *prescription* drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use. This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products. See Restatement (Second) of Torts, Section 388 (1965). Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.
>
> Reyes v. Wyeth Laboratories, 498 F.2d at 1276. (Emphasis in original.) Accord, Timm v. Upjohn Co., 624 F.2d 536, 538 (5th Cir.1980). Based on this sound reasoning, which we adopt, we answer the third certified question in the affirmative.

Stone v. Smith, Kline & French Laboratories, 447 So.2d 1301 (Ala.1984)(answering certified question).

Additionally, Bodie's claims of fraud fail for lack of substantial evidence. Bodie's testimony is that the representations he read in Purdue's pamphlet were the same "type of thing" that Dr. Mangieri told him and that what he read on Purdue's website "reinforced what was in the brochure and what Dr. Mangieri told [Bodie],

that [OxyContin] was safe and non-addictive, very few side effects, that type of thing" (emphasis supplied). Bodie did not testify that he remembers, specifically, what the representations were. In fact, he testified that he cannot give specifics; he can only discuss the representations "generally."

Analyzing Bodie's claims of what Purdue "told" him[7], there is no evidence that Bodie's testimony is anything more than a statement of his interpretation of the pamphlet and the website. The 2000 pamphlet, which Bodie claims is similar to the one he saw in 1998, does not state that OxyContin is "safe" and "non-addictive." Bodie's own testimony is that the website "reinforced" what was in the brochure. Thus, there is no substantial evidence that the pamphlet or the website said that OxyContin was "safe" and "non-addictive." Further, even if there were such substantial evidence as to Bodie, it would still be insufficient under the "learned intermediary" doctrine. The duty to warn extends to the physician, not the patient. It was his physician, not Bodie, that Purdue had a duty to warn. To hold otherwise would be to eviscerate the "learned intermediary" doctrine, because any claimant who had "surfed the Web" would be in a position to claim he/she had read information on the company's site that misled him into accepting his/her physician's medication prescription. The reasoning behind the "learned intermediary" doctrine is that the

[7] As opposed to Dr. Mangieri, discussed supra.

physician, who has specialized knowledge and training, and knowledge of the patient's medical condition, is in the best position to evaluate the risks and benefits of medication(s) and discuss those risks and benefits with the patient. If a patient, like Bodie, has read something somewhere else that raises a specific question (here addiction) about a medication's risks, or even if the patient has information, from any source, that causes the patient concern, the patient cannot remain silent, as to that issue, during patient/physician discussions and then claim to have been misled by the manufacturer. To permit this would put the patient in the role of the learned intermediary, and undercut the policy behind the doctrine. Stone v. Smith & Kline, supra.

To survive summary judgment, Bodie must produce "significantly probative" evidence of each element of his claim. Anderson v. Liberty Lobby, Inc., 477 U.S. at 249. Bodie cannon rest on mere allegations but must set forth evidence, sufficient to withstand a directed verdict, of "specific facts." Lujan v. Defenders of Wildlife, 504 U.S. at 561.

V. CONCLUSION

Bodie has failed to demonstrate that there is any genuine issue of material fact as to his claims based on strict liability. Bodie has failed to come forward with evidence that the alleged inadequacy of Purdue's warning to Bodie or his doctor

proximately caused Bodie's injury. Bodie's claim of fraud based on misrepresentations allegedly made to him is barred by the learned intermediary doctrine and also fails for lack of substantial evidence. Therefore, Purdue's Motion for Summary Judgment is due to be granted as to all counts of the Complaint.

A separate order will be entered contemporaneously herewith.

DONE and **ORDERED** this 13th day of June, 2005.

VIRGINIA EMERSON HOPKINS
United States District Judge